Christopher J. Jayne, MD, FACOG
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7580 Fannin, Suite 335A Houston TX 77054
713.795.0432 Fax: 713.795.0690
www.thecenterforwomenssexualhealth.com

THE CENTER FOR Women's Sexual Health

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:	Joel S. Hochman, et al
Ser. No.:	10/007,393
Filed:	October 26, 2001
For:	SYSTEM AND METHOD FOR TRANSDUCING, SENSING OR AFFECTING VAGINAL OR BODY CONDITIONS, AND/OR STIMULATING PERINEAL MUSCULATURE AND NERVES USING 2-WAY WIRELESS COMMUNICATIONS
Examiner:	Charles A. Marmor
Group:	3736

Commissioner for Patents
PO Box 1450
Alexandria VA 22313

DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUICE PATENT

I, Christopher J. Jayne, MD, declare as follows:

1. I am a Graduate with Honors from Buffalo School of Medicine, Buffalo New York, completed a residency in Obstetrics and Gynecology with Honors at Baylor College of Medicine, Houston Texas. I am Board Certified and a Fellow of the American College of Obstetricians and Gynecologists, and a Certified Sex Counselor by the American Association of Sex Educators Counselors and Therapists. I am the Medical Director of The Center for Women's Sexual Health at the Texas Medical Center in Houston Texas. I am a member of the Clinical Faculty at the Baylor College of Medicine in Houston Texas.

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2. I am familiar with the subject matter of the above-identified application. In addition, I have carefully studied U.S. Patent Publication 2002/0010390, Guice, et al.

3. Based on my knowledge and expertise, I hereby state that one of ordinary skill in the art would not consider the Guice reference when trying to provide a system and method for transducing vaginal conditions, affecting vaginal or body conditions, and stimulating perineal musculature and nerves in humans.

4. In particular, one of ordinary skill in the art would not look to Guice, which is clearly limited to use in animals, for any teaching or suggestion with respect to how to use or configure a device that is intended to be temporarily, i.e. in a non-implanted manner, inserted into a human vagina. As indicated, Guice is clearly limited to use in animals, which is very understandable given the significant anatomical differences between the vaginas of animals, and especially cows, and those of humans. This is supported by FDA standards and regulations and safety concerns that define implants, as will be discussed below.

5. Guice, for example in [0179], makes it clear that his device is adapted to be compressed and then expanded to keep the device in place in an ear canal or other cavity of an animal. Guice even suggests adhesive. A tool is needed to be able to install and remove the device from the animal.

6. In the medical and veterinary fields, the device of the above-identified application is not an implant. In contrast, the device of Guice must be considered an implant, and this is also true under FDA standards (see for example 21 CFR 812.3(d).) Thus, the device of Guice is in no way

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7. comparable to the temporarily insertable device of the above-identified application. Guice itself stresses that his device is a true implant. This is in large part due to the aforementioned differences in the anatomy of humans and animals, which requires that the device of Guice, in order to be effective, i.e. retained, must be implanted in the animal being monitored. Furthermore, as mentioned above, pursuant to FDA standards and definitions, the Guice device is an implant whereas the device of the above-identified application is not, as confirmed by the FDA device approval letter issued to Athena.

8. In conclusion, the Guice device is entirely unsuitable for human vaginal use, and one of ordinary skill in the art would not consider the Guice reference for any teaching or suggestion with regard to the configuration of a device that is to be temporarily inserted into the human vagina.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.

3/14/05

Christopher J. Jayne, MD, FACOG
AASECT Certified Sex Counselor
Medical Director, The Center for Women's Sexual Health

Date

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KURT R. WHARTON, MD

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Fax: 925-962-0003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joel S. Hochman, et al

Ser. No.: 10/007.393

Filed: October 26, 2001

For: SYSTEM AND METHOD FOR TRANSDUCING, SENSING OR AFFECTING VAGINAL OR BODY CONDITIONS, AND/OR STIMULATING PERINEAL MUSCULATURE AND NERVES USING 2-WAY WIRELESS COMMUNICATIONS

Examiner: Charles A, Marmon

Group: 3736

Commissioner for Patents
PO Box 1450

Alexandria VA 22313

DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUICE PATENT

I, Kurt R. Wharton MD, declare as follows:

1. I received an A.B. Degree in Physiology and Anatomy from the University of California at Berkeley in 1980. I received my Medical Degree from Boston University School of Medicine in 1984. After completing an Internship in Obstetrics and Gynecology at Mount Zion Hospital and Medical Center in 1985, I was a Resident in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco from 1985 through 1987. I served as Administrative Chief Resident during the academic year ending in 1988. I am currently Chairman, Department of Obstetrics and Gynecology at Alta Bates Summit Hospital in Berkeley, California. Additionally, I am the Site Director for Resident Education and I hold the Academic position of Associate Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. I am a Fellow of the American College of Obstetrics and Gynecology and I am Board Certified by the American Board of Obstetrics and Gynecology.

KURT R. WHARTON, MD

970 Dewing Ave. #201
Lafayette, CA 94549
Phone: 925-962-0002
Fax: 925-962-0003

2. I am familiar with the subject matter of the above-identified application. Additionally, I have reviewed the U.S. Patent Publication 2002/0010390, Guice, et al.

Based upon my training and professional expertise in Human Physiology, Obstetrics, Gynecology and Women's Health, I can state that no reference would be given to the Guice Patent by individuals attempting to develop biomedical systems intended to transduce vaginal conditions, affect vaginal or body conditions, or stimulate perineal neuromuscular tissues in humans.

3. By recognized clinical medical standards, the Guice Patent is a Patent for an implant. The Patent clearly identifies telesensor implant units intended for implantation in the ear, vagina rectum throat, nostril or subcutaneous tissues of an animal. The telesensors may also be implanted percutaneously. To be explicit, implants are devices surgically placed within or through tissues. Examples of human implants include the Norplant Contraceptive Devices and Cardiac Pacemakers. Human implants require surgical placement and removal. Paragraph 0164 of the Guice Patent states "the telesensor implant, which maybe exposed to animal tissue or fluids, should be biocompatible, and in many cases, should promote the ingrowth of tissue to help anchor the telesensor implant in the desired implant location." Obviously, such a device is unacceptable and inappropriate for the human vagina.
4. Examples of intravaginal medical devices that are not implants include contraceptive diaphragms, pessaries used to treat genital organ prolapse, and medical delivery systems such as the contraceptive NuvaRing and the estrogen releasing Estring. Such devices are placed into the vagina by the patient or healthcare provider and easily removed by the patient or healthcare provider. No surgery, tools or adhesives are required. The Patent requested by Athena allows for the development of temporarily insertable medical devices. This request is in no way comparable to the Guice implant device.
5. In summary, the Guice implant device is in no way appropriate or acceptable for use in the human vagina. Individuals developing medical devices for temporary placement within the human vagina would not consider the Guice reference.
6. I hereby declare that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so make are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.

Kurt R. Wharton MD — Date 3/10/05

I

FDA U.S. Food and Drug Administration Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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Title21 Part.Section *(e.g., 862.1385)* _____

CFR Title 21 - Food and Drugs: Parts 1 to 1405

(1) General enforcement regulations
(2) General administrative rulings and decisions
(3) Product jurisdiction
(5) Organization
(7) Enforcement policy

Full Text Search: _____

Enter a single word (e.g., catheter), an exact phrase (e.g., catheter line) or multiple words connected by *and* (e.g., catheter *and* tubing).

Search Regulation(s) Clear

Database Updated April 1, 2004

Exhibit 1
S/N 10/007,393
Amdt dated 3/23/05
Office Action dated 12/16/04

II

1 INTRODUCTION

WHAT IS A MEDICAL DEVICE
GENERAL CONTROLS
SPECIAL CONTROLS
PREMARKET NOTIFICATION
INVESTIGATIONAL DEVICE EXEMPTIONS
PREMARKET APPROVAL
NEW REGULATIONS

Chapter 1, "Introduction," is an overview of the medical device regulations with general information pertaining to premarket approval.

Products meeting the definition of a medical device under section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act) are regulated by the Food and Drug Administration (FDA). Medical devices are subject to general controls and other controls in the FD&C Act. General controls of the FD&C Act are the baseline requirements that apply to all medical device manufacturers. Unless specifically exempted, medical devices must be properly labeled and packaged, be cleared for marketing by the FDA, meet their labeling claims, and be manufactured in accordance with FDA's Quality Systems (QS) Regulation.

FDA regulates devices to assure their safety and effectiveness. To fulfill provisions of the FD&C Act, FDA develops and promulgates rules to regulate devices intended for human use. These regulations are published in the *Federal Register*. Final regulations are codified annually in the Code of Federal Regulations (CFR). Most medical device regulations are described in Title 21 CFR Parts 800 to 1299.

WHAT IS A MEDICAL DEVICE

The definition of a medical device appears in section 201(h) of the FD&C Act. A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopeia (USP), or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

CLASS	REGULATORY CONTROLS
Class I	General Controls
Class II	General Controls and Special Controls
Class III	General Controls and Premarket Approval

GENERAL CONTROLS

As noted above, general controls are the baseline requirements of the FD&C Act that apply to all medical devices. Unless specifically exempted by regulation, general controls contain requirements for device manufacturers or other designated persons to:

- comply with the registration and listing regulations in 21 CFR Part 807;
- comply with the labeling regulation in 21 CFR Part 801, 809 or 812;
- comply with the reporting regulations in 21 CFR Part 803 and 804;
- submit a premarket notification [510(k)] (21 CFR Part 807) to FDA; and
- design and produce devices under the Quality Systems Regulation (21 CFR Part 820).

The controls in the above list other than reporting regulations are briefly described in this chapter.

Registration and Listing

Section 510 of the FD&C Act requires that U.S. device manufacturers and distributors register their establishments with FDA on Form FDA-2891. All manufacturers are required to list the generic type of devices they have in U.S. commerce with FDA on Form FDA-2892. Establishment registration and medical device listing should be submitted prior to commercial distribution.

Labeling

All medical devices in U.S. commerce must be properly labeled. Device labeling requirements of the FD&C Act are found in the following parts of Title 21:

General Device Labeling	21 CFR Part 801
In Vitro Diagnostic Products	21 CFR Part 809

Investigational Device Exemptions ..... 21 CFR Part 812
Quality Systems Regulation ..... 21 CFR Part 820
General Electronic Products ..... 21 CFR Part 1010

Basic labeling requirements and recommended labeling for medical devices can be found in the ODE Blue Book Memorandum, "Device Labeling Guidance," #G91-1 (see Chapter 4), and in the booklet, *Labeling; Regulatory Requirements for Medical Devices*, available from the Division of Small Manufacturers Assistance (DSMA). Details concerning Blue Book memoranda are found in Chapter 4.

Good Manufacturing Practices

As required by section 520(f) of the FD&C Act, the Quality System (QS) regulation covers the methods used for, and the facilities and controls used for, the design, manufacture, labeling, packaging, storage, and installation of devices. The QS regulation is codified in 21 CFR Part 820. Some class I devices, such as an manual surgical instruments for general use, 21 CFR Section 878.4800, are exempt by regulation from most of the QS requirements.

The QS regulation contains general quality assurance (QA) or quality system requirements in areas of concern to all manufacturers of finished devices. Among other requirements, it covers organization and personnel; design practices and procedures; buildings and environmental control; design of labeling and packaging; controls for components, processes, packaging and labeling; finished device evaluation; distribution and installation; device and manufacturing records; complaint processing; and QA system audits.

SPECIAL CONTROLS

In addition to general controls, class II and III devices are subject to further requirements such as special controls and premarket approval, respectively.

Class II devices are defined in section 513(a)(1)(B) of the FD&C Act to include any device for which reasonable assurance of safety and effectiveness can be obtained by applying "special controls". Only general controls will apply to class II devices until special controls are established by regulation(s). Special controls may include special labeling requirements, mandatory performance standards, patient registries and postmarket surveillance.

PREMARKET NOTIFICATION

A premarket notification [510(k)] is a marketing application submitted to FDA to demonstrate that a medical device is as safe and as effective or substantially equivalent to a legally marketed device that was or is currently on the U.S. market and that does not require premarket approval. The premarket notification requirements are found in 21 CFR Part 807, Subpart E.

Most devices are cleared for commercial distribution in the U.S. by the premarket notification [510(k)] process. Most class I devices are exempt from the 510(k) requirement by regulation. However, they are not exempt from other general controls, such as establishment registration and device listing. Before marketing a medical device which is not exempt from the marketing clearance process, the manufacturer must submit a premarket notification [510(k)] or a premarket approval (PMA) application to FDA. The manufacturer cannot market the device in these cases, unless the firm receives a marketing clearance letter from FDA as stated in section 513(i)(1)(A) or section 515(d)(1)(A)(I) of the FD&C Act. Detailed guidance on the 510(k) requirements can be found in the manual, *Premarket Notification 510(k): Regulatory Requirements for Medical Devices.*

INVESTIGATIONAL DEVICE EXEMPTIONS

To allow manufacturers of devices intended solely for investigational use to ship devices for use on human subjects (clinical evaluation), the FD&C Act authorizes FDA to exempt these devices from certain requirements of the Act that would apply to devices in commercial distribution. Clinical evaluation of devices not cleared for marketing, unless exempt, requires an approved investigational device exemption (IDE) either by an institutional review board (IRB) or an IRB and FDA, informed consent for all patients, adequate monitoring and necessary records and reports. These requirements can be found in 21 CFR Parts 50, 56; and 812. Detailed guidance on the IDE requirements can be found in the *Investigational Device Exemption Manual.*

PREMARKET APPROVAL

Premarket approval (PMA) is the FDA process to evaluate the safety and effectiveness of class III devices. Class III is the most stringent regulatory category for medical devices. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act, in order to obtain marketing clearance.

Devices Subject to Premarket Approval

Under section 515 of the FD&C Act, all devices placed into class III by FDA are subject to premarket approval requirements. Premarket approval is the process of scientific and regulatory review to ensure the safety and effectiveness of class III devices. An approved PMA is, in effect, a private license granted to the applicant for marketing a particular medical device. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act and cannot be marketed. Premarket approval requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices.

Manufacturers of class III preamendments devices, devices that were in commercial distribution before May 28, 1976, are not required to submit a PMA until 30 months after the promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices that FDA determines are substantially equivalent to preamendments class III devices are subject to the same requirements as the preamendments devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with section 510(k) of the FD&C Act. Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into class I or II are "new" devices and fall automatically into class III. Before such devices can be marketed, they must have an approved premarket approval application or be reclassified into class I or class II.

Class III transitional devices and "new" devices are automatically classified into class III by statute and require premarket approval by FDA before they may be commercially distributed. Applicants may either submit a PMA or a Product Development Protocol (PDP), or they may petition FDA to reclassify the devices into class I or class II. Clinical studies in support of a PMA, a PDP, or a reclassification petition are subject to the Investigational Device Exemption (IDE) regulation.

The PMA requirements are found in 21 CFR Part 814. Not all class III devices require an approved PMA to be marketed at this time. Class III devices that are substantially equivalent to devices legally marketed before May 28, 1976, **and** do not currently require premarket approval may be marketed through the premarket notification [510(k)] process until FDA publishes a regulation requiring the submission of a premarket approval (PMA) application for those Class III devices.

The PMA Review Process

The review of a premarket approval application is a four-step review process consisting of:

- administrative and limited scientific review by FDA staff to determine completeness (filing review);
- in-depth scientific and regulatory review by appropriate FDA scientific and compliance personnel (in-depth review);
- review and recommendation by the appropriate advisory committee (panel review); and
- an FDA good manufacturing practices (GMP) inspection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

Ms. Barbara Sarkis
Chief Information Officer
Athena Feminine Technologies, Inc.
179 Moraga Way
ORINDA CA 94563

Re: K023905
Trade/Device Name: Athena Pelvic Muscle Trainer (PMT)
Regulation Number: 21 CFR §876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: 78 KPI
Dated: March 3, 2003
Received: March 4, 2003

Dear Ms. Sarkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Exhibit 3
S/N 10/007,393
Amdt dated 3/23/05
Office Action dated 12/16/04

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER: K023905

DEVICE NAME: ***Athena Pelvic Muscle Trainer***

INDICATIONS FOR USE:

The **Athena Pelvic Muscle Trainer** is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

David A. Krysmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023905

IV

FDA U.S. Food and Drug Administration Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TITLE 21--FOOD AND DRUGS

SUBCHAPTER H - MEDICAL DEVICES

PART 876 GASTROENTEROLOGY-UROLOGY DEVICES

See Related Information

Fed. Register Final Rules

Subpart A -- General Provisions

§ 876.1 - Scope.
§ 876.3 - Effective dates of requirement for premarket approval.
§ 876.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B -- Diagnostic Devices

§ 876.1075 - Gastroenterology-urology biopsy instrument.
§ 876.1300 - Ingestible telemetric gastrointestinal capsule imaging system.
§ 876.1400 - Stomach pH electrode.
§ 876.1500 - Endoscope and accessories.
§ 876.1620 - Urodynamics measurement system.
§ 876.1725 - Gastrointestinal motility monitoring system.
§ 876.1735 - Electrogastrography system.
§ 876.1800 - Urine flow or volume measuring system.

Subpart C -- Monitoring Devices

§ 876.2040 - Enuresis alarm.

Subpart D -- Prosthetic Devices

§ 876.3350 - Penile inflatable implant.
§ 876.3630 - Penile rigidity implant.
§ 876.3750 - Testicular prosthesis.

Exhibit 4
S/N 10/007,393
Amdt dated 3/23/05
Office Action dated 12/16/04

Subpart E -- Surgical Devices

§ 876.4020 - Fiberoptic light ureteral catheter.
§ 876.4270 - Colostomy rod.
§ 876.4300 - Endoscopic electrosurgical unit and accessories.
§ 876.4370 - Gastroenterology-urology evacuator.

§ 876.4400 - Hemorrhoidal ligator.
§ 876.4480 - Electrohydraulic lithotriptor.
§ 876.4500 - Mechanical lithotriptor.
§ 876.4530 - Gastroenterology-urology fiberoptic retractor.
§ 876.4560 - Ribdam.
§ 876.4590 - Interlocking urethral sound.
§ 876.4620 - Ureteral stent.
§ 876.4650 - Water jet renal stone dislodger system.
§ 876.4680 - Ureteral stone dislodger.
§ 876.4730 - Manual gastroenterology-urology surgical instrument and accessories.
§ 876.4770 - Urethrotome.
§ 876.4890 - Urological table and accessories.

Subpart F -- Therapeutic Devices
§ 876.5010 - Biliary catheter and accessories.
§ 876.5030 - Continent ileostomy catheter.
§ 876.5090 - Suprapubic urological catheter and accessories.
§ 876.5130 - Urological catheter and accessories.
§ 876.5160 - Urological clamp for males.
§ 876.5210 - Enema kit.
§ 876.5220 - Colonic irrigation system.
§ 876.5250 - Urine collector and accessories.
§ 876.5270 - Implanted electrical urinary continence device.
§ 876.5280 - Implanted mechanical/hydraulic urinary continence device.

§ 876.5310 - Nonimplanted, peripheral electrical continence device.
§ 876.5320 - Nonimplanted electrical continence device.
§ 876.5365 - Esophageal dilator.
§ 876.5450 - Rectal dilator.
§ 876.5470 - Ureteral dilator.
§ 876.5520 - Urethral dilator.
§ 876.5540 - Blood access device and accessories.
§ 876.5600 - Sorbent regenerated dialysate delivery system for hemodialysis.
§ 876.5630 - Peritoneal dialysis system and accessories.
§ 876.5665 - Water purification system for hemodialysis.
§ 876.5820 - Hemodialysis system and accessories.
§ 876.5830 - Hemodialyzer with disposable insert (Kiil type).
§ 876.5860 - High permeability hemodialysis system.
§ 876.5870 - Sorbent hemoperfusion system.
§ 876.5880 - Isolated kidney perfusion and transport system and accessories.
§ 876.5885 - Tissue culture media for human ex vivo tissue and cell culture processing applications.
§ 876.5895 - Ostomy irrigator.
§ 876.5900 - Ostomy pouch and accessories.
§ 876.5920 - Protective garment for incontinence.
§ 876.5955 - Peritoneo-venous shunt.
§ 876.5970 - Hernia support.

§ 876.5980 - Gastrointestinal tube and accessories.
§ 876.5990 - Extracorporeal shock wave lithotripter.

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.
Source: 48 FR 53023, Nov. 23, 1983, unless otherwise noted.

Database Updated April 1, 2004

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2004]
[CITE: 21CFR876.5320]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

Subpart F -- Therapeutic Devices

Sec. 876.5320 Nonimplanted electrical continence device.

(a) *Identification.* A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (§ 884.5940).

(b) *Classification.* Class II (performance standards).

Database Updated April 1, 2004

Exhibit 5
S/N 10/007,393
Amdt dated 3/23/05
Office Action dated 12/16/04

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[Code of Federal Regulations]
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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 812 -- INVESTIGATIONAL DEVICE EXEMPTIONS

Subpart A -- General Provisions

Sec. 812.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (sections 201-901, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301-392)).

(b) *Custom device* means a device that:

(1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;

(2) Is not generally available to, or generally used by, other physicians or dentists;

(3) Is not generally available in finished form for purchase or for dispensing upon prescription;

(4) Is not offered for commercial distribution through labeling or advertising; and

(5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

(c) *FDA* means the Food and Drug Administration.

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(d) *Implant* means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants" for purposes of this part.

(e) *Institution* means a person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as "facility" in section 520(g) of the act.

(f) *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving subjects and established, operated, and functioning in conformance with part 56. The term has the same meaning as "institutional review committee" in section 520(g) of the act.

(g) *Investigational device* means a device, including a transitional device, that is the object of an investigation.

(h) *Investigation* means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

(i) *Investigator* means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(j) *Monitor,* when used as a noun, means an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization. *Monitor,* when used as a verb, means to oversee an investigation.

(k) *Noninvasive,* when applied to a diagnostic device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. For purposes of this part, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

(l) *Person* includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity.

(m) *Significant risk device* means an investigational device that:

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 895 -- BANNED DEVICES

Subpart A -- General Provisions

Sec. 895.1 Scope.

(a) This part describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device.

(b) This part applies to any "device", as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

(c) A device that is made a banned device in accordance with this part is adulterated under section 501(g) of the act. A restricted device that is banned may also be misbranded under section 502(q) of the act.

(d) Although this part does not cover devices intended for animal use, the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device that is banned cannot avoid the ban by relabeling the device for veterinary use. A device that has been banned from human use but that also has a valid veterinary use may be marketed for use as a veterinary device only under the following conditions: The device shall comply with all requirements applicable to

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veterinary devices under the Federal Food, Drug, and Cosmetic Act and this chapter, and the label for the device shall bear the following statement: "For Veterinary Use Only. Caution: Federal law prohibits the distribution of this device for human use." A device so labeled, however, that is determined by the Food and Drug Administration to be intended for human use, will be considered to be a banned device. In determining whether such a device is intended for human use, the Food and Drug Administration will consider, among other things, the ultimate destination of the device.

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TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER I--ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 160_DEFINITION OF TERMS--Table of Contents

Sec. 160.1 Definitions.

For the purposes of this subchapter the following words, phrases, names and terms shall be construed, respectively, to mean:

Accredited veterinarian.\1\ A veterinarian approved by the Administrator in accordance with the provisions of part 161 of this subchapter to perform functions specified in subchapters B, C, and D of this chapter.

\1\ The provisions of subchapters B, C, and D of this chapter authorize Federal and State veterinarians and accredited veterinarians to perform specified functions. Full-time Federal (including military) and State employed veterinarians are authorized to perform such functions, pursuant to delegation of authority by the Administrator or cooperative agreements without specific accreditation under the provisions of this subchapter.

Administrator. The Administrator of the Animal and Plant Health Inspection Service or any individual authorized to act for the Administrator.

Animal, animals. All animals except humans, including but not limited to cattle, sheep, goats, other ruminants, swine, horses, asses, mules, zebras, birds, and poultry.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service, United States Department of Agriculture.

APHIS. The Animal and Plant Health Inspection Service.

Approved digital signature. Digital signatures approved by the Administrator for electronic transmission, for example, via a computer. To be approved, a digital signature must be able to verify the identity of the accredited veterinarian signing the document and indicate if the integrity of the data in the signed document was compromised.

Examine, examination. Physical study of an individual animal that enables an accredited veterinarian to determine if any abnormality in physical condition or bodily function is suggestive of clinical signs of communicable disease.

Inspect, inspection. Visual study of the physical appearance, physical condition, and behavior of animals (singly or in groups) that enables an accredited veterinarian to determine whether any abnormality in physical condition or bodily function is evident.

Issue. The distribution, including electronic transmission, of an official animal health document that has been signed.

Official certificate, form, record, report, tag, band, or other

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identification. Means any certificate, form, record, report, tag, band, or other identification, prescribed by statute or by regulations issued by the Administrator, for use by an accredited veterinarian performing official functions under this subchapter.

Regular health maintenance program. An arrangement between an accredited veterinarian and a livestock producer whereby the veterinarian inspects every animal on the premises of the producer at least once every 30 days.

Sign, (Signed). For an accredited veterinarian to put his or her signature in his or her own hand, or by means of an approved digital signature, on a certificate, form, record, or report. No certificate, form, record, or report is signed if:

(1) Someone other than the accredited veterinarian has signed it on behalf of or in the name of the accredited veterinarian, regardless of the authority granted them by the accredited veterinarian; or

(2) If any mechanical device, other than an approved digital signature, has been used to affix the signature.

State. Any State, the District of Columbia, Puerto Rico, Guam, the Northern Mariana Islands, the Virgin Islands of the United States, and any other territory or possession of the United States.

State Animal Health Official. The State animal health official who is responsible for the livestock and poultry disease control and eradication programs of a State.

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Veterinarian-in-Charge. The veterinary official of APHIS who is assigned by the Administrator to supervise and perform the official work of APHIS in a State or group of States.

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